Product ingredient source information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

DP BARCODE No.: D462235; **FILE SYMBOL/REG. No.**: 82633-AI; **PRODUCT NAME**: Sharda Spirodiclofen Technical; **DECISION No.**: 571497; **PC Code(s)**: 124871; **ACTION CODE**: R333; **FOOD Use**: Yes; **E-Sub#**: 60154

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DATE: December 20, 2021

SUBJECT: Product Chemistry Review of a New TGAI "Sharda Spirodiclofen Technical" (Basic CSF)

FROM: Dehui Duan, Chemist DDuan 12-20-2021
Product Chemistry Team, CITAB / RD (7505P)

THROUGH: Shyam Mathur, PhD sbmathur 12-20-2021
Product Chemistry Team Leader, CITAB / RD (7505P)

TO: Joseph Belsky / Gene Benbow, RM 07
IVB3 / RD (7505P)

REGISTRANT: SHARDA CROPCHEM LIMITED

MRID Number(s): 51422301-13

INTRODUCTION:

The registrant has submitted an application to register a new technical product "Sharda Spirodiclofen Technical" and claimed the similarity to Reg. No. 264-830. In support of this application, the registrant has submitted a Basic CSF dated 2/10/2021, Group A and Group B chemistry data with MRID Nos. 51422301-13 and a draft label.

The cited Basic CSF dated 12/7/2006 – Reg. No. 264-830, Nominal concentration (CL%): 98.22% (96.5-100%) – Manufacture site: [redacted].

The proposed Basic CSF dated 2/10/2021 – Reg. No. 82633-AI, Nominal concentration (CL%): 99.48% (96.5-100%) – Manufacture site: [redacted]

CITAB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF and assess a draft label and the similarity to the cited product.

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550: (product identity & composition)

The active ingredient was adequately described (MRID 51422301). The nominal concentration of the active ingredient (99.48 %) provided on the basic CSF (dated 2/10/2021) is the same as the average derived from the five-batch preliminary analysis results (99.48 %, from Page 10 of 143 in the Confidential Attachment of MRID 51422302). The nominal concentration on the basic CSF concurs with that on the proposed label. The information presented meets the data requirements for 40 CFR 158.320.

830.1600: (description of materials used to produce the product)

Safety Data Sheets (SDSs) of all the starting materials, and their specifications and suppliers were provided in the study (MRID 51422301). The information presented meets the data requirements for 40 CFR 158.325.

830.1620 (description of production process)

A detailed description of the production process, vessels and equipment, in process control measures and a flow chart were included in MRID 51422301. The information presented meets the data requirements for 40 CFR 158.330.

830.1670 (discussion on the formation of impurities)

Potential impurities were identified and quantified as part of the five-batch analysis (MRID 51422302). The formation and identities of the impurities were fully discussed in MRID 51422301. One impurity was found present at levels greater than 0.1%. The information presented meets the data requirements for 40 CFR 158.335.

830.1700 (preliminary analysis)

The study was conducted by ChemService S.r.l. Controlli e Ricerche, GLP Studies Department Via F.lli Beltrami, 15 20026 Novate Milanese - MI - (Italy). Results are presented for a five-batch analysis using HPLC-DAD with external standard calibration for the active ingredient and significant impurities. All reference standards were certified. The identification for the Active Ingredient was confirmed by IR and 1H and 13C NMR spectra. The identification for impurities was performed by using HPLC/MS/DAD against corresponding analytical standards. The relevant impurities were investigated by GC-FID validated method. [redacted] content was analyzed by Karl Fischer titration. The analytical methods for impurities were validated with respect to specificity, linearity, system precision, repeatability (precision) and recovery (accuracy), LOQ and LOD. The information presented meets the data requirements for 40 CFR 158.345.

830.1750 (certified limits)

The proposed upper and lower certified limits for the active ingredient and impurities on the proposed basic CSF (dated 2/10/2021) are within the range of the guideline OCSPP 830.1750 recommendation. The nominal concentrations of impurities are the same as averages on five-batch analysis table. The information presented meets the data requirements for 40 CFR 158.350.

830.1800 (enforcement analytical method)

The methods for the determination of the active ingredient were validated with respect to specificity, linearity, repeatability and precision (MRID 51422303). The information presented meets the data requirements for 40 CFR 158.355.

2. Group B guidelines (physical-chemical properties):

<table>
<tr><th>GLN</th><th>Requirement</th><th>MRID</th><th>Status</th><th>Result or Deficiency</th></tr>
<tr><td>830.6302</td><td>Color</td><td>51422312</td><td>A</td><td>white</td></tr>
<tr><td>830.6303</td><td>Physical state</td><td>51422312</td><td>A</td><td>Needle crystal</td></tr>
<tr><td>830.6304</td><td>Odor</td><td>51422312</td><td>A</td><td>Characteristic odour</td></tr>
<tr><td>830.6313</td><td>Stability to normal and elevated temperatures, metals, and metal ions</td><td>51422312</td><td>A</td><td>This product was stable to normal and elevated temperatures, aluminum sheet, Zinc Sheet, Copper Sheet and polyethylene sheet.</td></tr>
<tr><td>830.6314</td><td>Oxidation/reduction: chemical incompatibility</td><td>51422312</td><td>A</td><td>Product is compatible with NaOH, H_2O_2 and Zinc.</td></tr>
<tr><td>830.6315</td><td>Flammability</td><td>51422312</td><td>A</td><td>Product is not a flammable substance.</td></tr>
<tr><td>830.6316</td><td>Explodability</td><td>51422312</td><td>A</td><td>Product is not explosive.</td></tr>
<tr><td>830.6317</td><td>One Year storage stability</td><td>51422311</td><td>A</td><td>Product is stable at 54°C for 14 days when stored in aluminum bags.</td></tr>
<tr><td>830.6319</td><td>Miscibility</td><td>51422313</td><td>W</td><td>This is a technical grade active ingredient (TGAI) and the product will not be diluted with a petroleum solvent; therefore, these data are not required.</td></tr>
<tr><td>830.6320</td><td>One Year corrosion characteristics</td><td>51422311</td><td>A</td><td>No corrosion was found when product was stored in aluminum bags at 54°C for 14 days.</td></tr>
<tr><td>830.7000</td><td>pH</td><td>51422312</td><td>A</td><td>6.3 of a 1% w/v aqueous dilution</td></tr>
<tr><td>830.7050</td><td>UV/Visible absorption</td><td>51422312</td><td>A</td><td>
<table>
<tr><th rowspan="2">λ maximum (nm)</th><th colspan="3">ε molar absorption coefficient (L/mol x cm⁻¹)</th></tr>
<tr><th>Neutral</th><th>Acid</th><th>Basic</th></tr>
<tr><td>218</td><td>19116</td><td>20923</td><td>-</td></tr>
<tr><td>254</td><td>6357</td><td>6366</td><td>15489</td></tr>
<tr><td>208</td><td>-</td><td>-</td><td>15506</td></tr>
<tr><td>290 (default)</td><td>125</td><td>-</td><td>4657</td></tr>
</table>
</td></tr>
<tr><td>830.7100</td><td>Viscosity</td><td>51422313</td><td>W</td><td>This product is not a liquid; therefore it is requested that this requirement be waived.</td></tr>
<tr><td>830.7200</td><td>Melting point</td><td>51422312</td><td>A</td><td>94.9 °C</td></tr>
<tr><td>830.7220</td><td>Boiling point</td><td>51422313</td><td>A</td><td>Product is a solid.</td></tr>
<tr><td>830.7300</td><td>Density</td><td>51422312</td><td>A</td><td>1.2902 g/mL at 20 °C</td></tr>
<tr><td>830.7370</td><td>Dissociation constants in water (DC)</td><td>51422313</td><td>W</td><td>Product does not dissociate.</td></tr>
</table>

GLN	Requirement	MRID	Status	Result or Deficiency
830.7520	Particle size, fiber length, and diameter distribution	51422313	W	This product is a water soluble technical grade active ingredient; therefore, it is requested that this requirement be waived.
830.7550	Partition coefficient	51422312	A	Log P_{ow} = 5.24
830.7840	Water solubility	51422312	A	Solubility in water 0.05 mg/L at 20°C n-Heptane 20-25 g/L Xylene > 250 g/L Dichloromethane > 250 g/L 2-Propanol 40-50 g/L Acetone > 250 g/L Ethyl acetate > 250 g/L
830.7950	Vapor pressure	51422312	A	P = 7.72 x 10^{-4} Pa (20°C)
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required); W = waivers requested				

CONCLUSIONS:

The CITAB has reviewed the proposed basic CSF (dated 2/10/2021) and the supporting Group A and Group B data for Sharda Spirodiclofen Technical and has concluded that:

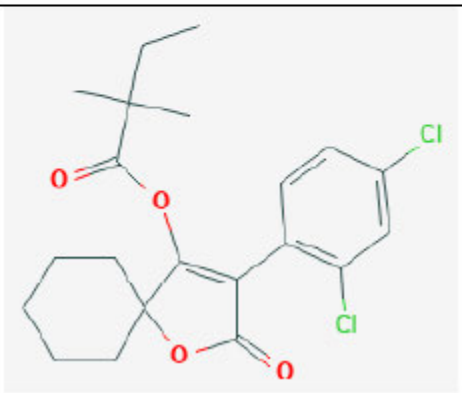
1. The product chemistry data submitted for Group A guidelines are acceptable.

2. The product chemistry data submitted for Group B guidelines are acceptable.

3. The proposed Basic CSF dated 2/10/2021 is acceptable and supported by five-batch analysis. It contains [redacted] impurities while the cited basic CSF of Reg. No. 264-830 dated 12/7/2006 contains [redacted] impurities. They have [redacted] impurities in common.

4. The content on the draft label is the same as nominal concentrations on the proposed. There is no additional recommendation for the label.

Active Ingredient

Product Name:	Sharda Spirodiclofen Technical
Active Ingredient:	Spirodiclofen
Chemical Name (IUPAC):	[3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl] 2,2-dimethylbutanoate
CAS No.:	148477-71-8
Molecular Formula:	$C_{21}H_{24}Cl_2O_4$
Molecular Weight:	411.3 g/mol
Nominal Concentration:	99.48% (nominal)
Structural formula:	

The analytical method was shown to be specific for active ingredient in the Spirodiclofen Technical samples.

The range tested for Spirodiclofen, from 29.70 to 69.30 µg/mL (± 40 % of the solution concentration used for the quantification analysis), was found to be linear (correlation coefficient > 0.99).

The relative standard deviation was 0.12% for Spirodiclofen and the Horwitz RSDr was 1.34 at a Spirodiclofen concentration of 99.5 % w/w. Since the relative standard deviation was lower than the Horwitz RSDr, the repeatability test for this active ingredient was acceptable.

Data and results were used to determine the following precision.

Spirodiclofen : 99.5 ± 0.5 % w/w

According to the SANCO/3030/99 rev. 4 guideline, the determination of accuracy for the active ingredient in the technical test item, in terms of recovery data, is not required, but is judged acceptable based on the results of the specificity and the precision results.

Pages 7-12*Manufacturing process information may be entitled to confidential treatment*